K043297

FEB 2 3 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MEDICON 2.4 MANDIBULAR RECONSTRUCTION PLATING SYSTEM

1. **General Information**

Proprietary Name:	Medicon 2.4 Mandibular Reconstruction Plating System
Common Name:	Mandibular Fixation System
Classification Name:	Bone Plate
Classification Code(s):	JEY, 872.4760
Submitter:	Medicon, E.G. Gaensaecker 15 Tuttlingen, D-78532 Germany Tel.: 011-49-7462-2009-31 Fax: 011-49-7462-2009-9931
Est. Reg. No.	8010099
Contact Person:	Angelika Scherp Regulatory Affairs Tel.: 011-31-20-428-9591
Summary Preparation Date:	November 22, 2004

2. **Device Description**

The Medicon 2.4 Mandibular Reconstruction Plating System includes titanium plates, titanium alloy Star*Grip screws, templates and accompanying instruments and accessories. Plates are 2.5 mm thick and include flat and preformed straight, angled, and full mandible configurations in lengths from 6 screw holes to 29 screw holes. Plates can accept 2.4 mm diameter locking screws or standard, non-locking 2.4 mm and 2.7 mm diameter bone screws. All screws are self-tapping. The 2.7 mm diameter screws can also be used as emergency screws.

The device is supplied non-sterile and must be sterilized prior to use. Moist heat sterilization is recommended.

Instruments and accessories available are: screwdrivers, screw holding forceps, twist drills, drill guide, depth gauge, cheek retractor with drill guide

and trocar, plate bender, plate bending forceps, plate bending pliers, cutting lever, plate holding forceps, plate cutting forceps, tap, templates, storage and sterilization trays for implants and instruments.

3. **Intended Use**

The Medicon 2.4 Mandibular Reconstruction Plating System is intended to be used during emergency and nonemergency situations for replacement of mandibular bone, primary and secondary functionally stable defect bridging of mandibular defects, anatomically-positioned fixation of mandibular bone stumps, and fixation of bone grafts.

4. **Substantial Equivalence**

The Medicon 2.4 Mandibular Reconstruction Plating System is substantially equivalent to the previously cleared Medicon Titanium Mandibular Reconstruction System (K951689), with the following modifications:

a) Plates
- Change in material from titanium alloy to titanium
- Thickness increased from 2 mm to 2.5 mm
- Thread added to holes
- Product line expanded to include anatomically preformed plates

b) Screws
- Product line expanded to include 2.4-mm-diameter screws with and without locking function

c) Instruments
- Product line expanded to include cutting lever, plate cutting forceps and tap.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2005

Medicon, E.G.
C/O Ms. Angelika Scherp
Director, Regulatory Affairs
Business Support International
Amstel 320-I
Amsterdam, 1017AP
NETHERLANDS

Re: K043297
Trade/Device Name: Medicon 2.4 Mandibular Reconstruction Plating System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: January 4, 2005
Received: January 31, 2005

Dear Ms. Scherp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

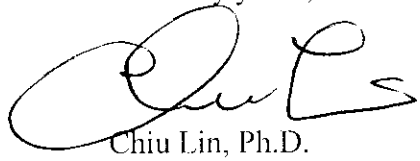
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043297

Device Name: Medicon 2.4 Mandibular Reconstruction Plating System

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Office of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(510(k) Number K043297